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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,187	06/15/2001	Annamaria Naggi	DI-5373 CON	8866

29200 7590 10/16/2003

BAXTER HEALTHCARE CORPORATION
RENAL DIVISION
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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/16/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,187

Applicant(s)

NAGGI ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Response dated June 19, 2003

1. In the Response filed June 19, 2003, claims 1, 4, 10, and 16 were amended. Applicant presented arguments directed to the rejection of claims 5-22 under 35 U.S.C. 101; the rejection of claims 2-4 under 35 U.S.C. 112, second paragraph; and the rejections of claims 1-22 under 35 U.S.C. 103(a). Claims 1-22 are pending. An action on the merits of claims 1-22 is contained herein below.
2. The rejection of claims 5-22 under 35 U.S.C. 101 is maintained for the reasons of record set forth in the Office Action dated December 3, 2002.
3. The rejection of claims 2-4 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicant's arguments set forth in the Response dated June 19, 2003.
4. The rejections of claims 1-22 under 35 U.S.C. § 103(a), is maintained for the reasons of record set forth in the Office Action dated December 3, 2002.

Objections/Rejections Set For the in Office Action dated December 3, 2002

5. Claims 5-22 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-22 of copending Application No. 09/206,063.
6. Claims 1-4 were rejected under 35 U.S.C. 103(a) as being unpatentable over Milner US 4,886,789 (Milner) in view of Bellini et al. EP 0 612 528 A1 (Bellini).

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7. Claims 5-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Solomons, Organic Chemistry, 2nd edition, 1976, p. 890 (Solomons), in combination with Aman et al., Carbohydrates in Food, p. 195, 1996 (Aman), and Horn et al. US 3,974,034 (Horn).

Response to Arguments

35 U.S.C. 101

8. Applicant's arguments filed June 19, 2003 have been fully considered but they are not persuasive.

Applicant argues that the instantly disclosed methods are patentably distinct from the methods of pending Application No. 09/206,063.

The examiner respectfully disagrees. Contrary to applicant's assertion, the instantly claimed methods are not drawn to a method administering an autoclavable osmotic agent. The claims are instead drawn to methods of preparing a stabilized osmotic agent by treating starch with either NaBH₄ or NaOCl. It is further noted that the instant claims do not require "administration" of anything.

35 U.S.C. 103(a)

9. Applicant's arguments filed June 19, 2003 have been fully considered but they are not persuasive.

10. Regarding claims 1-4, applicant argues that the art of record does not teach glucose polymers that are linked by bonds that include at least 85%, by number, α -1,4 bonds.

The examiner respectfully disagrees with applicant's mischaracterization of the art of record, specifically Milner. Milner teaches a glucose polymer preparation consisting of predominantly of glucose polymers with a degree of polymerization from 10 to 40 (column 3, lines 1-6). The polymers are linked by 1-4 alpha and 1-6 alpha-D-glycosidic chemical bonds. Milner further teaches that the starch from which the glucose polymer is obtained contains not more than 5% of 1,6-linkages (column 7, lines 12-19).

11. Regarding claims 5-22, arguments set forth by applicant are not germane. Contrary to applicant's assertion, the instantly claimed methods are not drawn to a method administering an autoclavable osmotic agent. The claims are instead drawn to methods of preparing a stabilized osmotic agent by treating starch with either NaBH_4 or NaOCl . It is further noted that the instant claims do not require the "administration" of any compound, composition, or other material. Process claims are defined by the active, positive steps delimiting how process is actually practiced. In the instant case, the active steps required to practice the invention are: 1) providing a solution of starch dissolved in water and 2) adding NaBH_4 or NaOCl to the starch solution. These steps are taught by the prior art of record. In the absence of some proof of a secondary nature to obviate the rejection as set forth in the Office Action dated December 3, 2002, or of some specific limitations which would tip the scale of patentability in the favor of the instantly claimed invention, it would have been obvious to one of ordinary skill in this art at the time of the invention to reduce or oxidize starch using NaBH_4 or NaOCl , respectively.

Conclusion

12. Claims 1-22 are pending. Claims 1-22 are rejected. No claims are allowed.
13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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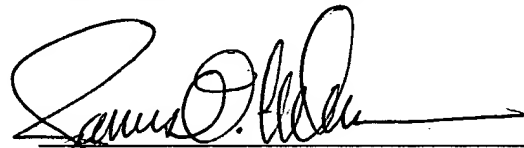
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623


James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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